

 sphincter-relaxer, an anti-ischemic agent, a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice.

REMARKS

The Office Action of July 16, 2002 has been received and considered. In the Office Action, claims 2-5 and 11 were withdrawn from consideration as being drawn to a non-elected embodiment. Claims 1 and 6-10 were rejected under 35 U.S.C. §102 and 35 U.S.C. §103. Claims 6 and 9 were also rejected under 35 U.S.C. §112, second paragraph.

Claims 1, 6 and 8-10 have been amended. Claims 2-5 and 11 have been cancelled. Claims 1 and 6-10 remain pending. Reconsideration of the application as amended is requested.

An aspect of the present invention relates to a composition for being applied to a breast nipple in preparation for collecting ductal fluid from the breast. This composition is used to prepare the nipple and its ductal orifices so that increased amounts of ductal fluid can be collected. The recited composition can include at least two of the following: an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, muscle-constricting agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice.

Another aspect of the invention includes a system comprising a ductal access tool and a composition for being applied to the breast nipple. The composition used with the ductal access tool recited in claim 9 can include at least two of the following: an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, muscle-constricting

agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice. The composition recited in claim 10 can include one of the above-listed elements of the composition in combination with a ductal access tool that is preloaded with an anesthetic.

Claims 6 and 8 were rejected under 35 U.S.C. §102(a) as being anticipated by CN 1,252,293 to Tian in view of Merk Index (1983). Tian is cited to disclose the use of a medicated pad containing alcohol that can act on a breast. The Merk Index was cited to teach that alcohol is an antiseptic agent. The publication to Tian discloses a Chinese therapeutic preparation for applying to a breast in order to plump up a breast, while also preventing and treating diseases. The specific composition disclosed by Tian includes natural extracts, juices and the above-mentioned alcohol.

Claim 6 has been amended as shown above. Claim 6 no longer recites that the composition includes an antiseptic agent. Instead, claim 6 now recites that the composition includes elements that enhance the ability of a person to collect fluid from a duct or identify the perimeter of a duct. No element recited in Tian performs these functions. Hence, Tian does not anticipate claims 6 and 8. Withdrawal of the rejection is requested. Additionally, nothing in the prior art would have suggested modifying the therapeutic composition of Tian to arrive at the system recited in claims 6 and 8.

Claims 1, 6 and 7 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,560,553 to Zupan that discloses an eucalyptol for enhancing skin permeation of bio-affecting agents. It was asserted in the Office Action that Zupan

discloses a composition comprising a local anesthetic and beta-blockers. Zupan also discloses the use of other agents that can be applied to the body in the eucalyptol.

Claims 1 and 6 have been amended as shown above. Claims 1 and 6 each recite a composition including elements that, for example, enhance the ability of an individual to identify the location of a duct or to collect fluid from within a duct. Fluid collection according to the present invention can be enhanced, for example, by relaxing the muscles associated with the duct or stimulating lactation. The patent to Zupan does not disclose the elements of the composition recited in claims 1 and 6 or the need to perform the functions achieved by the elements of the composition recited in claims 1 and 6. Therefore, the patent to Zupan does not anticipate claims 1, 6 and 7. Withdrawal of the rejection is requested.

It would not have been obvious to modify the composition disclosed in the patent to Zupan to include the elements of the composition recited in claims 1 and 6 because the patent to Zupan does not relate to or suggest collecting ductal fluid from a breast duct. As a result, modifying the disclosure of the patent to Zupan to arrive at the composition recited in claim 1 and the system recited in claim 6 could only be based on impermissible hindsight.

Claims 9 and 10 were rejected under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) as being unpatentable over the disclosure of Tabar et al. that is relied upon to disclose a ductal access tool containing methylene blue dye and a contrast material that are used in performing galactography. The mixture of the methylene blue and the contrast material is introduced into a breast duct in order to identify the perimeter of the duct and show masses that may be present within the duct.

Claims 9 and 10 have been amended. These claims recite a system including a ductal access tool and a composition including elements that enhance the ability of an

individual to collect fluid from within a duct or identify the location of a duct. As discussed above, fluid collection can be enhanced by relaxing the muscles associated with the duct or by stimulating lactation. While Tabar arguably discloses the use of a ductal access tool including a staining agent (methylene blue) for identifying the perimeter of a duct, it does not disclose the use of any of the recited elements of the composition that increase the ability of a person to obtain fluid from within a duct. Therefore, the publication of Tabar does not anticipate claims 9 or 10.

Similarly, it would not have been obvious to modify the system of Tabar to include the recited elements of the composition that increase fluid retrieval, etc. because Tabar is not concerned with obtaining ductal fluids. Instead, Tabar only relates to introducing fluids into a duct. Therefore, one of ordinary skill would not have been motivated to modify the galactography system of Tabar to arrive at the system recited in claims 9 and 10. Withdrawal of the rejections is requested.

For all of the above-discussed reasons, Applicants respectfully submit that claims 1, 6 and 8-10 are allowable and that the application is now in condition for allowance. A notice to this effect is earnestly solicited.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicants' attorney, the Examiner is invited to contact Applicants' attorney at the number noted below.

Respectfully submitted,

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Marked-up copy of claims for U.S. Patent Application S.N. 09/876,144

Please amend claims 1, 6 and 8-10 as follows:

1. (Amended) A composition [to contact] for being applied to a breast nipple [and to prepare a breast for] in preparation for collecting ductal fluid from the breast, said composition [collection] comprising[, in] bioactive amounts[, two or more] of at least two of the following: [an anesthetic agent, a detergent, an exfoliating agent, an antiseptic agent, a dekeratinyzing agent,] an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, muscle-constricting agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, [a beta-blocker,] a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice.

6. (Amended) A system comprising:

an aliquot of a bioactive composition for applying to a nipple surface, said composition comprising [a mixture of one or more of] at least two of the following: [an anesthetic, a detergent, an exfoliating agent, an antiseptic agent, a dekeratinizing agent,] an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, a muscle-constricting agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, [a beta-blocker,] a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice[, in a formulation to contact a nipple surface].

9. A system as in claim 6, further comprising a pad [of] having a geometry [to circumscribe] sized to circumscribe a breast nipple [to] and enclose a bioactive agent in contact with a nipple surface and cover the nipple surface [for sufficient time for] so that the bioactive agent [to] can act on the nipple surface.

9. A system comprising a ductal access tool for collecting fluid from within a breast duct and a composition [of a formulation] capable of coating a tip of the ductal access tool to contact a ductal orifice, said composition comprising at least two of the following: [one or more of an anesthetic, a detergent, an exfoliating agent, an antiseptic agent, a dekeratinizing agent,] an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, a muscle-constricting agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, [a beta-blocker,] a calcium channel blocker, a dye or stain to mark the nipple surface excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice.

10. (Amended) A system comprising a ductal access tool preloaded with a solution comprising an anesthetic for infusion into an accessed breast duct and a composition [of a formulation] capable of coating a tip of the tool, said composition comprising [one or more] at least two of [an anesthetic, a detergent, an exfoliating agent, an antiseptic agent, a dekeratinizing agent,] an orifice-dilating agent, a vaso-dilator, a muscle-relaxing agent, a muscle-constricting agent, a lactation-stimulating agent, a secretion-stimulating agent, a sphincter-relaxer, an anti-ischemic agent, [a beta-blocker,] a calcium channel blocker, a dye or stain to mark the nipple surface

excluding ductal orifices, a dye or stain to mark a perimeter of a ductal orifice, and a dye or stain to mark a ductal orifice.